SEP 1 6 2003

K031632

Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.93

Submitter	Implant Innovations, Inc. 4555 Riverside Palm Beach Gardens, FL 33410
Contact	Jacquelyn A. Hughes, RAC Director, Regulatory Affairs and Quality Assurance Implant Innovations, Inc. 4555 Riverside Palm Beach Gardens, FL 33410 Tel. 561-776-6819 Fax. 561-776-6852 Email jhughes@3implant.com
Date Prepared	May 23, 2003
Device Name	*3i* IOL™ Implants
Classification Name	Endosseous Dental Implant
Device Classification	Class III Dental Devices Panel 21 CFR § 872.3640
Predicate Devices	K014235 - OSSEOTITE® NT™ Dental Implants K972444 - *3i* Innovative Implants and Cover Screws K935544 – Threaded Self-Tapping Threaded Implants K980549 – OSSEOTITE Dental Implants K983347 - OSSEOTITE Dental Implants K022009 – *3i* Dental Implants
Performance	Performance standards have not been established by the FDA under Section 514 of the Federal Food, Drug and Cosmetic Act.

Device Description	The *3i* IOL™ Dental Implants are offered in both externally hexed and internally connected designs. The devices are tapered implants designed to mimic the shape and form of a natural tooth.
Indications for Use	*3i* IOL Dental Implants are indicated for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment.
Technological Characteristics	The *3i* IOL Dental Implants contain features and functions which are similar to the currently available OSSEOTITE NT™ Implants and *3i* Innovative Implants and Cover Screws.
Conclusion	The *3i* IOL Dental Implants are substantially equivalent to the legally marketed OSSEOTITE NT Implants and *3i* Innovative Implants and Cover Screws.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 2003

Ms. Jacquelyn A. Hughes
Director Regulatory Affairs
Implant Innovations, Incorporation
4555 Riverside Drive
Palm Brach Gardens, Florida 33410

Re: K031632
Trade/Device Name: Osseotite IOL™ Implants
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implants
Regulatory Class: III
Product Code: DZE
Dated: May 23, 2003
Received: June 26, 2003

Dear Ms. Hughes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031632

Device Name: *3i* IOL Dental Implants

Indications for Use:

3i dental implants are indicated for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ken Mulay for MSL

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031632

Prescription Use: X OR Over the Counter Use: _____
(Per 21 CFR 801.109)